REMARKS

A. Status of the Claims

Claims 12-34 were pending at the time of the Action. Claims 12-20 (the Group I claims) were provisionally elected with traverse in a telephone interview with the Examiner on February 7, 2007. Consequently, in the Action, claims 21-34 were withdrawn from consideration by the Examiner as being drawn to a non-elected invention(s). Claim 12 has been amended. Support for the amendment can be found in the specification as originally filed. *See, e.g.*, pages 2 and 3. Claims 14-16 and 25-27 to clarify that the values (*e.g.* 10,000 to 90,000 g/mol) are molecular weights and not degrees of polymerization, which are not *per se* measured in g/mol. New claim 35 has been added. Support for new claim 35 can be found in the specification at, for example, pages 2-4. Claim 35 corresponds to the Group I invention. Claims 12-35 are currently pending with claims 12-20 being withdrawn from consideration by the Examiner as being drawn to a non-elected invention(s).

B. Response to Restriction Requirement

In response to the Restriction Requirement that the Examiner imposed, Applicants elect the Group I invention (*i.e.,* claims 12-20), with traverse, thereby affirming the provisional election by Applicants' representative in a telephone interview with the Examiner on February 7, 2007.[1]

Applicants assert that the Group IV invention (*i.e.,* claim 34) should be joined with the Group I claims for further examination in this case because a search of the Group I and Group IV inventions would not constitute a "serious burden" on the Examiner. MPEP § 803 ("If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions").

Claim 12 of Group I recites a composition comprising a water-soluble complex of hypericin and a poly-N-vinylamide or a water-soluble compound of hypericin and a poly-N-vinylamide, wherein the hypericin is a synthetic hypericin or a hypericin isolated from a plant. Claim 34 of Group IV recites a method of diagnosing cancer, comprising obtaining a composition as set forth in claim 12, and using that composition in a method of photophysical or photodynamic diagnosis for cancer. If the use of a composition of claim 12 as recited by claim 34 is in the prior art (which Applicants do not admit), any search by the Examiner regarding the composition of claim 12 should reveal art related to such a use. As such, in viewing the search results relating to the composition of claim 12, no "serious burden" would be placed upon the Examiner to determine if the use of the composition falls into the scope of claim 34. Thus, under MPEP § 803, claim 34 (the Group IV claim) should be rejoined with claims 12-20 (the Group I claims).

If Applicants' request to rejoin the Group I and Group IV inventions is denied, Applicants reserve the right to have the Group IV claims considered for rejoinder under the provisions of MPEP § 821.04 *et seq.* upon the allowance of a Group I claim(s). The Group I claims are drawn to a product (that is, a composition), and the Group IV claims are drawn to a process of using that product. "[I]f applicant elects a claim(s) directed to a product which is subsequently found allowable, withdrawn process [of using] claims which depend from or otherwise require all the limitations of an allowable product claim ***will be considered*** for rejoinder." *Id.* at § 804.21(b).

C. The Claims Are Novel Over Cody

Claims 12-14, 19 and 20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cody (U.S. Patent No. 6,063,401). The Action contends that Cody teaches a soft gelatin capsule

[1] Applicants' arguments against the Restriction Requirement do not create an estoppel against Applicants and are not an admission that the restricted Groups are either patentably distinct or patentably indistinct from one another. This applies to all of Applicants' arguments against all of the Restrictions.

containing *Hypericum perforatum* and polyvinylpyrrolidone. Action at page 4. Applicants traverse this rejection.

Current claim 12 is directed to a composition comprising a water-soluble complex of hypericin and a poly-N-vinylamide or a water-soluble compound of hypericin and a poly-N-vinylamide, wherein the hypericin is a synthetic hypericin or an isolated hypericin. As described in the present specification pure hypericin may be isolated from a plant or synthesized (Specification, p. 3). Hypericin present in plants or plant extracts that are composed of several hundred substances are not suitable for the presently claimed invention (Specification, p. 3). Also as noted in the specification at page 2, hypericin is characterized as "lipidic" and "water-insoluble"—properties that "make the application in the human body difficult." The present inventors, however, have demonstrated that hypericin can be rendered water-soluble when formed as a complex or compound with poly-N-vinylamide. *Id.* As a result of complexing or bonding hypericin with PVP, a water-soluble form of hypericin is available for the first time in physiologically relevant amounts (Specification, p. 2).

Cody discusses hypericin only in the context of being comprised in dried *Hypericum perforatum* (col. 4, lines 40-48) or a liquid extract of *Hypericum perforatum* (col. 4, line 50 through col. 5, line 8). In other words, the hypericin of Cody is neither synthetic nor isolated. For example, the hypericin content of dried *Hypericum perforatum* or an extract thereof is described by Cody as follows:

> When dried herbs are used in the present composition... the *Hypericum perforatum* component comprises from about 95% to about 5% by weight of the total composition, wherein the dried *Hypericum perforatum* is standardized to comprise 0.3% by weight of Hypericin....
>
> When... *Hypericum perforatum* [is] prepared using extraction methods, the composition of the present invention comprises... *Hypericum perforatum* extract in the amount from about 0.05% to about 40% by volume of the total composition, wherein the *Hypericum perforatum* extract is standardized to comprise 0.3% Hypericin.

Col. 4, lines 40-46 and col. 5, lines 1-7, respectively. Neither of these preparations teach or suggest an isolated or synthetic hypericin as recited in the current claims.

Furthermore, while polyvinylpyrrolidone is mentioned in Cody as a suitable solvent into which *Hypericum perforatum* may be added, there does not appear to be any teaching of a water-soluble complex of hypericin and polyvinylpyrrolidone. Cody appears to disclose only organic solvents for use in the liquid core of its gelatin capsules. *See* col. 5, line 59 through col. 6, line 6. As such, Cody also does not teach water-soluble complex or compound of hypericin and a poly-N-vinylamide.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. Because Cody does not teach a composition comprising a water-soluble complex of hypericin and a poly-N-vinylamide or a water-soluble compound of hypericin and a poly-N-vinylamide, wherein the hypericin is a synthetic hypericin or an isolated hypericin, Cody does not anticipate the presently claimed invention. Applicants, therefore, request the withdrawal of the rejection.

D. The Claims Are Novel Over Bombardelli *et al.*

Claims 12-14 and 19 are rejected under 35 U.S.C. § 102(e) as anticipated by Bombardelli *et al.* (U.S. Pub. No. 2001/0000326). The Action asserts that Bombardelli *et al.* teach a tablet containing *Hypericum perforatum* and polyvinylpyrrolidone. Action at page 4. Applicants traverse this rejection.

As discussed above with respect to the Cody reference, Bombardelli *et al.* also fail to teach synthetic hypericin or isolated hypericin. Bombardelli *et al.* are concerned with the preparation of *Hypericum perforatum* extracts (*see, e.g.*, Title, Abstract) and no mention is made of isolating any particular component, such as hypericin. For example, the greatest weight

percentage of hypericin in an extract prepared by methods according to Bombardelli *et al.* is from 0.5 to 1.2 percent (*see* paragraph [0015] and claim 16).

In addition, Bombardelli *et al.* also fail to teach a composition comprising a water-soluble complex of hypericin and a poly-N-vinylamide or a water-soluble compound of hypericin and a poly-N-vinylamide. Not only is there no discussion of hypericin forming a complex or bonding with a poly-N-vinylamide, there is no discussion of such a complex or compound being water-soluble. In fact, Bombardelli *et al.* teach that the aqueous phase is removed from the extract of *Hypericum perforatum* and the extract is dried under a vacuum (Example 2, para. [0039]). Moreover, the only context in which it appears that a poly-N-vinylamide is mentioned in the presence of a *Hypericum perforatum* extract is in paragraph [0041], wherein a tablet comprises 5 mg of polyvinylpyrrolidone and 300 mg of the dried extract. There is no suggestion that the polyvinylpyrrolidone and the hypericin of the extract come together to form a water-soluble complex or compound. Indeed, water is not mentioned in the tablet of paragraph [0041], and, as discussed above, the *Hypericum perforatum* extract prepared according to Bobardelli's Example 2 has been dried.

In view of the above, Bombardelli *et al.* do not teach every element of the claimed invention and, therefore, cannot support an anticipation rejection. Applicants, therefore, request the withdrawal of the rejection.

E. The Claims Are Novel Over Castillo

Claims 12-14 and 19 are rejected under 35 U.S.C. § 102(e) as anticipated by Castillo (U.S. Pub. No. 2002/0150637). The Action asserts that *Hypericum perforatum* and polyvinylpyrrolidone are together in a tablet. Action at page 4. Applicants respectfully traverse this rejection.

Castillo fails to teach every element of the claimed invention. In particular, Castillo fails to teach a synthetic hypericin or an isolated hypericin. Castillo does not discuss the isolation of hypericin free from other components in a *Hypericum perforatum* extract. As discussed above, Hypericin present in plants or plant extracts that are composed of several hundred substances are not suitable for the presently claimed invention (*see* Specification, p. 3).

In addition, Castillo, also fails to teach a water-soluble complex or compound of hypericin and a poly-N-vinylamide. In paragraph [0116], Castillo teaches that 120 mg of *Hypericum perforatum* and 8 mg of polyvinylpyrrolidone and other components are mixed as powders and ultimately compressed into tablet form on a tablet machine. This, however, does not teach a water-soluble complex or compound of hypericin and a poly-N-vinylamide.

In view of the above, claims 12-14 and 19 are novel over Castillo. Applicants, therefore, request the withdrawal of the rejection.

F. Cody in View of JP 409262279 Do Not Render Claims 12-20 Obvious

Claims 12-20 are rejected under 35 U.S.C. § 103(a) as being obvious over Cody in view of JP 409262279 ("the '279 publication"). The Action asserts that Cody teaches a soft gelatin capsule containing *Hypericum perforatum* and polyvinylpyrrolidone. Action at page 5. The Action further asserts that while Cody does not teach that the polyvinylpyrrolidone is 10,000-40,000 g/mol, the '279 publication makes up for this deficiency. *Id.* Applicants respectfully traverse this rejection.

As discussed in section C above, the arguments of which are incorporated into this section, Cody does not teach every element of the claimed invention. In particular, Cody fails to teach a composition comprising a water-soluble complex of hypericin and a poly-N-vinylamide or a water-soluble compound of hypericin and a poly-N-vinylamide, and further fails to teach synthetic hypericin or an isolated hypericin. These shortcomings are not overcome by the '279

publication, as the '279 publication does not discuss hypericin, much less synthetic hypericin or hypericin isolated from a plant, and also fails to teach or suggest the formation of a composition comprising a water-soluble complex or compound of hypericin and a poly-N-vinylamide. As such, these references fail to teach every element of the claimed invention and cannot support an obviousness rejection. Applicants, therefore, request the withdrawal of the rejection.

G. Bombardelli *et al.* or Castillo *et al.* in View of Cody and JP 409262279 Do Not Render Claims 12-20 Obvious

The Action rejects claims 12-20 under 35 U.S.C. § 103(a) as obvious over Bombardelli *et al.* or Castillo in view of Cody and the '279 publication. The Action asserts that Bombardelli *et al.* and Castillo each teach a tablet containing *Hypericum perforatum* and polyvinylpyrrolidone. Action at page 6. The Action further states that while Bombardelli *et al.* and Castillo do not teach that the polyvinylpyrrolidone has the claimed molecular weight, the other amounts in the claims, or a composition in gel form, Cody and the '279 publication make up for these deficiencies. Applicants respectfully traverse this rejection.

As discussed above in sections D and E, the contents of each of which are incorporated into this section, Bombardelli *et al.* and Castillo each fail to teach every element of the claimed invention. In particular, each of these references fails to teach a composition comprising a water-soluble complex of hypericin and a poly-N-vinylamide or a water-soluble compound of hypericin and a poly-N-vinylamide, and each fails to teach a composition comprising synthetic hypericin or isolated hypericin. As discussed in section C above, the contents of which are incorporated into this section, Cody also suffers from these deficiencies. The '279 publication does not supplement the combination of the Bombardelli *et al.*, Castillo and Cody references with the necessary information to teach all elements of the claimed invention. The '279 publication not only does not discuss hypericin, but it does not discuss the formation of a composition comprising a water-soluble complex or compound of hypericin and a poly-N-vinylamide. As

such, these references taken together fail to teach every element of the claimed invention and cannot support an obviousness rejection under MPEP § 2143. Applicants, therefore, request the withdrawal of the rejection.

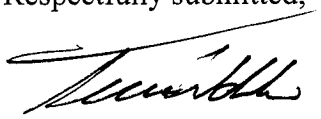
H. Conclusion

In view of the foregoing, Applicants submit that the claims are in condition for allowance and an early indication to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-5654 with any questions, comments or suggestions relating to the referenced patent application.

Interview Summary

An interview between Examiner Meller and Applicant's representative took place on February 7, 2007, in which claims 12-20 (the Group I claims) were provisionally elected with traverse. Additional interviews between Examiner Meller and Applicant's representative took place on May 21, 2007 and June 13, 2007, to discuss the claims and the references cited in the Office Action dated February 22, 2007. No agreement was reached during the May 21, 2007 and June 13, 2007 interviews.

Respectfully submitted,



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